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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/346,794	07/02/99	SNUTCH T	NMEDP001-2

HM12/0227
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EXAMINER	
BASI,N	
ART UNIT	**PAPER NUMBER**
1646	12

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/346,794	Snutch et al
Examiner	**Group Art Unit**
Nirmal. S. Basi	1646

☒ Responsive to communication(s) filed on *Dec 8, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) *1-20 and 22-24* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-24* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Response to Restriction requirement filed 12/8/00 has been entered.

Election/Restriction

2. Applicant's election with traverse of Group XVI (Claims 21), in Paper No. 11 (12/8/00), is acknowledged. The traversal is on the ground(s) that, "There is no basis for treating each nucleotide and amino acid sequence as a separate invention; all are related by the property that they encode T-type calcium channels". This is not found persuasive because each of Groups I-XV, pertaining to nucleic acid or polypeptide, is directed to a distinct invention because the the inventions of each group are physically and functionally distinct chemical entities, comprising distinct calcium channels, which are capable of separate use and manufacture (see paper number 8, 10/4/00). That each distinct compound is a member of the same heterogenous family is irrelevant, they are all still completely different products. Further, a search of the "Groups" would not be co-extensive particularly with regard to the literature search. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejection, 35 U.S.C. 112, second paragraph

3. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite because the name "α_1 subunit of a mammalian T-type calcium channel" has not been defined in the claims and specification so as to allow the metes and bounds of the claims to be determined. The specification discloses, "The terms "α_1 subunit" or "α_1 calcium channel" refer to a protein subunit of a calcium channel which is responsible for pore formation and contains the voltage sensor and binding sites for calcium channel agonists and antagonists. Such subunits may be independently functional as calcium channels or may require the presence of other subunit types for complete functionality". The terms "α_1 subunit" has been defined only in general functional terms and lacks structural information so as to allow the metes and bounds of the claim to be determined. It is not clear which polypeptide sequences would be considered "α_1 subunit of a mammalian T-type calcium channel", and considering the applicants definitions of "α_1 subunit" it is not clear what determines what "protein subunit of a calcium channel which is responsible for pore formation", what are the binding sites for calcium channel agonists and antagonists, so as to allow the metes and bounds of the claims to be determined. Further the term "α_1 subunit" also encompasses subunits encoded by DNA molecules "which hybridize under conditions of medium (or higher) hybridization stringency with one or another of the specific sequences disclosed in this application". It is not clear what is the structure of said "α_1 subunit". Therefore, name "α_1 subunit of a mammalian T-type calcium channel" does not sufficiently serve to characterize said subunit.

Further claim 21 is indefinite because it is unclear what interaction is being evaluated and what parameters are used to evaluate the interaction.

Claim 21 is also indefinite because the preamble recites "A method of identifying compounds capable of acting as agonists or antagonists for T-type mammalian calcium channels" but the claim does not state how thr goal of the preamble is achieved. It is not clear how an agonist or antagonist is identified and what interaction determines if a compound is an agonist as compared to an antagonist. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further

research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the "α_1 subunit of a mammalian T-type calcium channel". For example, the specification at page 1 asserts that, "The present invention relates to novel mammalian (including human) calcium channel compositions, and to the expression of these compositions in cell lines for use in evaluating calcium channel function and behavior of compositions which modulate calcium channel function". Further stated is, "In addition to the variety of normal physiological functions mediated by calcium channels, they are also implicated in a number of human disorders". The specification, in Table 5, discloses the electrophysical and pharmacological properties of known α_1 subunits of calcium channels which have been "cloned to date". The α_1 subunits are associated with calcium channels of the type L, N, and P/Q. The present invention, "provides sequences for novel mammalian calcium channel subunits of T-type calcium channels", which are labeled as α_{1G}, α_{1H} and α_{1I} subunits". The specification states that "these subunits, either alone or assembled with other proteins, can produce functional calcium channels, which can be evaluated in model cell lines to determine the properties of the channels containing the subunits of the invention. Theses cell lines can be used to evaluate the effects of pharmaceuticals and /or toxic

substances on calcium channels incorporating α_{1G}, α_{1H} and α_{1I} subunits" (page 7) . The specification discloses polynucleotide encoding "α_1 subunit" may be useful as probes in screening human cDNA libraries for genes encoding these novel calcium channel subunits, the α_1 subunit may be used to generate antibodies, cell lines expressing α_1 subunit may be used to evaluate compounds as pharmacological modifiers of the function of novel calcium channel subunits, (page 8). Further disclosed novel calcium channel subunits may be associated with a human genetic disease including, but not limited to; epilepsy, migraine, ataxia, hypertension, arrhythmia, angina, depression, small lung carcinoma. Lambert-Eaton syndrome, characterization of such associations and ultimately diagnosis of associated diseases can be carried out with probes which bind to the wild-type or defective forms of the novel calcium channels (page 9).

The utilities asserted by Applicant are not substantial or specific. Neither the specification nor the art of record disclose any disease states treatable by the novel polynucleotides, of instant invention, or polypeptides encoded by them. Similarly, neither the specification nor the art of record disclose any instances where blocking any effects of said polynucleotides or polypeptides encoded by them reduces the effect of a disease state. Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use especially when the complete sequence of the claimed invention is not known. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real

world" context of use for the disclosed polynucleotides or the polypeptides encoded by them, further experimentation is necessary to attribute a utility to the claimed polynucleotides and encoded polypeptides. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Since the utilities asserted by Applicant for polynucleotide and polypeptide of instant application are not substantial or specific, then it follows that the method of claim 21 (method of identifying compounds capable of acting a s agonists or antagonists for T-type mammalian calcium channels), also has no utility. Similarly, agonists and antagonists identified by said method have no utility.

8. Claim 21 is are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Further, even if one of skill in the art were enabled to use the instant method, one would not be enabled to practice the method as broadly claimed because the general structural attributes definitive of α_1-subunit for T-type calcium channels are not taught in the specification, nor known in the art (also see rejection under 35 U.S.C. 112, second paragraph above). One would be enabled to make T-type channels using only the instant α_{1G}, α_{1H} or α_{1I} subunits.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
February 22, 2001